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10/812,884	03/31/2004	Shoichi Kanayama	251157US2SX	4570

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EXAMINER	
CWERN, JONATHAN	

ART UNIT	PAPER NUMBER
3737	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/812,884	KANAYAMA ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/16/08 has been entered.

Claim Objections

Claims 1-15 and 26-28 are objected to because of the following informalities:

In claim 1, line 8, the term "transducer elements convert" does not match the tense of the rest of the claim language.

In claim 1, line 15, it is unclear what is meant by the term "reception directivity", or if this term is misspelled.

In claim 26, (i) is referred to as ultrasound imaging elements and (ii) as photoacoustic irradiation and detection elements. In step c, the photoacoustic signal is detected using ultrasound transducers. In step 3, an ultrasound image is displayed by using ultrasound transducers with the photoacoustic detection transducers. The term "photoacoustic detection transducers" lacks antecedent basis, as it was previously referred to as "ultrasound transducer" in step c. The use of this different terminology is confusing. It is suggested to use one term throughout the claims. For example,

"ultrasound transducers" could refer to (i), and "photoacoustic detection transducers" could refer to (ii).

Also in claim 26, "the photoacoustic vascularization image" lacks antecedent basis. Step c merely detects a signal.

In claim 27, it is unclear which wavelength is referred to by "the wavelength", as claim 26 uses the plural "wavelengths".

In claim 28, the word "photoacoustic" is spelled with a hyphen, when it was previously not in earlier claims. The spelling should be consistent throughout the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-23, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruger (US 2003/0069491) in view of Unger et al. (US 5977538).

As per claims 1, 2, 3, and 4, Kruger discloses a non-invasive imaging apparatus comprising: a light-generating unit (electromagnetic energy from an external source, paragraph 30), light irradiation and waveguide means (18, 84)for guiding and radiating light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) at a plurality of wavelengths (2-12 centimeters, paragraph 4), a plurality of vertically and horizontally arrayed electroacoustic transducer elements with gaps between elements (24, 32, Figure 3), transmission means for transmitting Ultrasonic waves (52, 54), reception means for generating a reception signal from the ultrasonic waves (52, 56), signal processing means for generating volume data by processing a reception signal corresponding to acoustic waves generated in the subject by light radiated from the irradiation unit (46, 48), and signal processing means for generating volume data about a subject morphology by processing a reception signal corresponding to echoes generated in the subject upon transmission of the ultrasonic waves (US imaging system, 52). Kruger further discloses a waveguide (84) discretely arranged between arrayed electroacoustic transducer elements in a handheld unit (86-1 through 86-8; see also Figure 7), surrounded by eight elements. Kruger does not

explicitly disclose using optical fiber for the waveguide means and does not explicitly disclose a plurality of waveguides in the handheld unit. Kruger et al. also fail to show the plurality of optical fibers arranged in the intervals between horizontally and vertically arrayed transducer elements.

Unger et al. disclose an optoacoustic imaging system. Unger et al. teach that the optical fibers can be arranged horizontally, vertically, or in a circle, in between or around the transducer elements (column 5, lines 1-45 and Figures 3A-3F). Such configurations are old and well known in the art, and the benefits of such configurations are also well known. For example, one arrangement could allow for the lateral spatial resolution of the images produced to be improved, or one arrangement could be used to obtain more uniform and/or more powerful illumination. The specific configuration of the optical fibers and transducer elements is an obvious design choice which can be selected by one of ordinary skill in the art.

Optical fibers are a well-known waveguide means for infrared and visible light electromagnetic radiation. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger to use optical fiber as the waveguide means as taught by Unger et al., in order to investigate the subject properties at infrared and visible wavelengths. Furthermore, the exact number of elements surrounding the waveguide is an obvious design choice.

As per claims 5 and 6, Kruger further discloses scanning means (scanning system, paragraph 37), accomplished by rotating the waveguides (18) and detector

array (24) to multiple angular positions (paragraph 31) and further discloses generating a reception signal corresponding to acoustic waves generated by irradiation of the light (TACT system and receiver, 46 and 48), from electrical signals from a predetermined number of transducer elements (24, 32) near an end portion of a waveguide (Figure 1).

As per claim 7, and as applied to claim 2 above, Kruger further discloses radiating light beams (electromagnetic radiation, see abstract) from not less than two optical fibers (at least eight waveguides, Figure 6A) whose end portions are spaced apart by not less than a predetermined distance.

As per claim 8, and as applied to claim 7 above, Kruger further discloses generating a reception signal corresponding to acoustic waves generated by irradiation of the light (TACT system and receiver, 46 and 48), from electrical signals from a predetermined number of transducer elements (24, 32) near an end portion of an optical fiber (waveguide, Figure 1).

As per claim 9, and as applied to claim 2 above, Kruger further discloses simultaneously radiating light (synchronized electromagnetic radiation, paragraph 16) from a plurality of end portions of optical fibers (waveguides, Figure 1-; eight positions, Figure 6).

As per claim 10, and as applied to claim 9 above, Kruger further discloses generating a reception signal from electrical signals (TACT system and receiver, 46 and 48), from a predetermined number of transducer elements (24, 32) near an end portion of an optical fiber (waveguide, Figure 1).

As per claims 11 and 12, Kruger further discloses alternately (separately) performing (Simultaneously, or as a separate imaging modality, paragraph 37) the irradiation of light and the transmission of ultrasonic waves.

As per claim 13, Kruger further discloses forming a 2-dimensional image (paragraph 10). Furthermore, forming a 2-dimensional image from a 3-dimensional volume of data inherently requires selecting a single slice from the 3-dimensional volume.

As per claims 14 and 15, Kruger further discloses displaying (display, 50)living body function image data (TACT data, paragraph 37) and morphology image data (ultrasound image, paragraph 37), with said morphology image data superimposed on (overlaid, paragraph 37) said living body function image data on the display. Kruger does not explicitly disclose displaying the images side by side. It would have been obvious to a person having ordinary skill in the art at the time of the invention to display the images side by side, as it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japiske,* 86 USPQ 70.

As per claim 16, Kruger discloses an imaging method comprising: irradiating a subject to be examined with light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) containing a specific wavelength component (2-12 cm, paragraph 4), receiving acoustic waves using a plurality of two-dimensionally arranged electroacoustic transducer elements (24, 32), transmitting ultrasonic waves in a plurality of directions (54), receiving echoes from the ultrasonic waves (56), generating volume data about a tissue morphology (US imaging system, 52), and

generating volume data about a living body function on the basis of the acoustic waves (TACT system and receiver, 46 and 48). Kruger further discloses a waveguide (84) between arrayed electroacoustic transducer elements in a handheld unit (86-1 through 86-8; see also Figure 7).

As per claim 17, Kruger further discloses sequentially radiating light (electromagnetic radiation) from said plurality of radiators by rotating the apparatus in order to collect signals from a sequence of multiple angular positions paragraph 31).

As per claims 18 and 19, Kruger further discloses simultaneously radiating light (synchronized electromagnetic radiation, paragraph 16) from a predetermined number of discrete positions (eight positions, Figure 6).

As per claim 20, Kruger further discloses alternately (separately) performing (Simultaneously, or as a separate imaging modality, paragraph 37) the irradiation of light and the transmission of ultrasonic waves.

As per claims 21-23, Kruger discloses a subject-information imaging apparatus comprising: irradiation means for irradiation a subject to be examined with light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides), ultrasonic transmission means for transmitting ultrasonic waves (54), a plurality of two-dimensionally arrayed electroacoustic conversion means for receiving an acoustic wave (transducer elements 24, 32, Figure 3), first image data generating means on the basis of the acoustic wave (TACT system and receiver, 48, and 46) generated in the subject upon the irradiation of light, second image data generating means based on the ultrasonic waves (56), display means (display, 50) for displaying

the first image data and the second image data, wherein the ultrasonic wave transmission means is partly commonly used as the electroacoustic conversion means (the sensors on array 24 may be used for conventional ultrasound imaging of the subject tissue, paragraph 37), and wherein the display means displays the first image data and the second image data on the same monitor (an ultrasound image of the tissue may be .. overlaid with ...the TACT-generated image, paragraph 37). Kruger further discloses a plurality of vertically and horizontally arrayed electroacoustic transducer elements with gaps between elements. Kruger does not explicitly disclose arraying the elements in the form of a grid array. Grid arrays are an old and well known technique of arranging sensor elements in an array. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger to place the elements in a grid array for ease of manufacture of the handheld unit disclosed in Kruger (Figure 7).

As per claim 29, the phrase "for diagnosing disease such as breast cancer" is intended use language and is not given patentable weight because it is not further reflected in the body of the claim. Kruger discloses an apparatus comprising: a light-generating unit (electromagnetic energy from an external source, paragraph 30), light irradiation and waveguide means (18, 84) for guiding and radiating light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) at a plurality of wavelengths (1-12 centimeters, paragraph 4), first electroacoustic conversion means (two-dimensional array of transducer elements 24, 32), first image

data generating means (46, 48), transmission means for transmitting ultrasonic waves (52, 54), second image data generating means on the basis of the second electroacoustic conversion means (US imaging system, 52), and a display means for displaying the first image data and the second image data (an ultrasound image of the tissue may be .. overlaid with ...the TACT-generated image, paragraph 37). Kruger further discloses a plurality of vertically and horizontally arrayed electroacoustic transducer elements with gaps between elements (24, 32, Figure 3). Kruger does not explicitly disclose a second electroacoustic conversion means for converting components of the ultrasonic waves transmitted by the ultrasonic wave transmission means but, rather, uses the first electroacoustic conversion means for converting both the acoustic waves and the ultrasonic waves.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Kruger to use separate electroacoustic conversion means as it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art, Nerwin v. Erlichman, 168 USPQ 177, 179. Furthermore, separate arrays of transducer elements would avoid the need for filtering of the two signals.

As per claim 30, the phrase "for determining a distribution of the concentration of an analyte" is intended use language and is not given patentable weight because it is not further reflected in the body of the claim. Kruger discloses an apparatus comprising: a light-generating unit (electromagnetic energy from an external source, paragraph 30),

light irradiation and waveguide means (18, 84)for guiding and radiating light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) at a plurality of wavelengths (paragraph 4), first electroacoustic conversion means (two-dimensional array of transducer elements 24, 32), first image data generating means (46, 48), transmission means for transmitting ultrasonic waves (52, 54), on means (86), second image data generating means on the basis of the second electroacoustic conversion means (US imaging system, 52), and a display means for 0 displaying the first image data and the second image data (an ultrasound image of the tissue may be .. overlaid with ...the TACT-generated image, paragraph 37).

Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruger (US 2003/0069491) in view of Unger et al. (US 5977538) and Chou (US 6049728).

As per claims 26 and 28, Kruger discloses a method of imaging the human breast (radiation in a breast, paragraph 27) comprising: a probe having two-dimensionally arrayed ultrasound imaging elements (Figure 7), irradiating the tissue with light pulses (pulsed radiation, paragraph 9) to generate a photoacoustic signal, detecting the photoacoustic signal using ultrasound transducers (24, 32), and generating and displaying an ultrasound image and a photoacoustic image (an ultrasound image of the tissue may be overlaid with the TACT-generated image, paragraph 37), using common acoustic and ultrasound detection elements (86). Kruger

further discloses a waveguide (84) irradiation unit integrated with electroacoustic transducer elements in a handheld unit (86-1 through 86-8; see also Figure 7). Kruger does not explicitly disclose separate acoustic and ultrasonic detection elements but, rather, uses same set of detection elements to detect both signals and does not explicitly disclose irradiating the tissue with light having wavelengths within an absorption spectral band of hemoglobin. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Kruger to use separate electroacoustic conversion means as it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Nerwin v. Erlichman, 168 USPQ 177, 179. Furthermore, separate arrays of transducer elements would avoid the need for filtering of the two signals.

Chou discloses using a wavelength corresponding to an absorption spectral band of hemoglobin (electromagnetic energy at wavelengths corresponding to the absorption characteristics of the analyte, column 3, lines 13-15; monitor...Hemoglobin, column 4, line 37). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger by using a wavelength corresponding to an absorption spectral peak of hemoglobin in order to generate images with high specificity to the presence of blood within the breast.

Kruger et al. also fail to show the plurality of optical fibers arranged in the intervals between horizontally and vertically arrayed transducer elements.

Unger et al. disclose an optoacoustic imaging system. Unger et al. teach that the optical fibers can be arranged horizontally, vertically, or in a circle, in between or around

the transducer elements (column 5, lines 1-45 and Figures 3A-3F). Such configurations are old and well known in the art, and the benefits of such configurations are also well known. For example, one arrangement could allow for the lateral spatial resolution of the images produced to be improved, or one arrangement could be used to obtain more uniform and/or more powerful illumination. The specific configuration of the optical fibers and transducer elements is an obvious design choice which can be selected by one of ordinary skill in the art.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruger (US 2003/0069491) in view of Unger et al. (US 5977538) and Chou (US 6049728) as applied to claim 26 above, and further in view of Diab et al (US 2003/0097049).

As per claim 27, and as applied to claim 26 above, the Kruger/Chou combination, as applied to claims 26 above, discloses all the elements of the claimed invention except that it does not explicitly disclose using a wavelength of light in the spectral range between 530 nm and 1300 nm. Diab et al discloses a relative absorption spectrum of oxygenated and de-oxygenated hemoglobin from 300 nm to 1000 nm showing various absorption peaks and valleys, etc. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the combination of Kruger/Chou to use wavelengths in the range from 530 nm to 1300 nm, as this range is very close to the spectral absorption range for hemoglobin disclosed in Diab et al and therefore wavelengths in this range could be chosen to maximize the

signal from the hemoglobin or to provide best contrast between oxygenated and de-oxygenated hemoglobin.

Response to Arguments

Applicant's arguments with respect to claims 1-23 and 26-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. G. C./
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737